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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,953	03/17/2004	Bozidar Ferek-petric	P-9468.00	4208

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,953	FEREK-PETRIC, BOZIDAR	
	Examiner	Art Unit	
	Jessica L. Reidel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Claims 1-17 in the reply filed on October 13, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 1-2 and 8 appear to be informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

3. Claim 7 is objected to because of the following informalities: there appears to be a typographical error in the second line of the Claim. The Examiner suggests changing the Claim to read, "said transvenous delivery mechanism comprises one of: a stylet, a single lumen delivery catheter *and* a guidewire. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 15 recites the limitation "the computer readable medium" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because Claim 14 recites the limitation "a programmable medium".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-2, 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumann et al. (U.S. 5,836,987). As to Claim 1, Baumann discloses a system comprising a processor-based electronic cardiac pacing engine 10 (see Baumann Fig. 1 and column 5, lines 46-49) and a single accelerometer, read as a mechanical sensor 50, adapted to detect a global signal associated with various atrial and ventricular events, and provide an output signal corresponding to that detected global signal to the processor-based electronic cardiac pacing engine 10. The Examiner takes the position that an accelerometer type mechanical sensor 50 that detects and provides a "global signal" associated with various atrial and ventricular events, such as cardiac wall accelerations and decelerations, encompasses detecting and providing an output

signal corresponding to contractions of at least a left atrial chamber, a left ventricular chamber and a right ventricular chamber (see Baumann column 6, lines 11-32).

The Examiner regards the limitation of a system "for continuously sensing mechanical activity of a heart and adjusting a pacing therapy based on the sensed mechanical activity" as intended use and notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The Examiner takes the position that in addition to the arguments presented above, Baumann is capable of performing the intended use of "continuously sensing mechanical activity of a heart and adjusting a pacing therapy based on the sensed mechanical activity" (see Baumann Abstract and column 2, lines 58-65).

9. As to Claim 2, Baumann discloses that mechanical sensor 50 may alternatively be attached to lead 20 adapted to be coupled to a portion of the superior vena cava, read as a cardiac vein (see Baumann Fig. 1 and column 6, lines 22-25).

10. As to Claim 12, Baumann discloses that the processor-based electronic cardiac pacing engine 10 comprises an implantable pulse generator 42 (see Baumann Fig. 1 and column 2, lines 61-65).

11. As to Claim 14, Baumann discloses that the processor-based electronic cardiac pacing engine 10 comprises a programmable medium 34 for executing computer readable instructions (see Baumann column 5, lines 36-45).

12. As to Claim 15, Baumann discloses that the processor-based electronic cardiac pacing engine 10 establishes the optimal timing interval which includes the timing interval between intrinsic or paced stimulations in preselected chambers of the heart, for any of the following

pacing modes: A--A pacing, the V--V pacing and A-V pacing (see Baumann column 5, lines 49-55).

13. Claims 1-5 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chinchoy (U.S. 6,885,889).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

14. As to Claim 1, Chinchoy discloses a system comprising a processor-based electronic cardiac pacing engine 14 and a single mechanical sensor 62, located on lead 52, adapted to detect cardiac contractions (see Chinchoy Abstract, Fig. 1A and column 6, lines 9-12). In reference to the location of mechanical sensor 62 as depicted in Chinchoy Fig. 1A, The Examiner takes the position that the mechanical sensor 62 is adapted to detect cardiac contractions of at least a left atrial chamber, a left ventricular chamber, and a right ventricular chamber based on Applicant's disclosure page 18, paragraph 49 and Applicant's Fig. 7. Chinchoy further discloses that mechanical sensor 62 provides an output signal corresponding to the detected cardiac contractions to the processor-based electronic cardiac pacing engine 14 (see Chinchoy column 6, lines 58-61 and column 8, lines 7-20).

The Examiner regards the limitation of a system "for continuously sensing mechanical activity of a heart and adjusting a pacing therapy based on the sensed mechanical activity" as

intended use and notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In addition, Chinchoy discloses that the system 14 is capable of performing the intended use (see Chinchoy Abstract).

15. As to Claim 2, Chinchoy discloses that single mechanical sensor 62, located on endocardial left ventricular coronary sinus lead 52, is adapted to be coupled to a portion of a coronary sinus ostium, a portion of a coronary sinus and a portion of a cardiac vein (see Chinchoy Fig. 1A, column 5, lines 66-67 and column 6, lines 1-8 and lines 27-41)

16. As to Claim 3, Chinchoy discloses an additional mechanical sensor 60, located on right ventricular lead 32, adapted to mechanically couple to a discrete portion of the right ventricular chamber such as the right ventricular apical region (see Chinchoy Fig. 1A and column 5, lines 59-63).

17. As to Claim 4, Chinchoy discloses that the single mechanical sensor 62 may comprise either an accelerometer or a tensiometric type sensor (see Chinchoy column 6, lines 12-17 and lines 21-26).

18. As to Claim 5, Chinchoy discloses that the accelerometer mechanical sensor 62 is preferably uniaxial, read as a single axis accelerometer, or biaxial or triaxial, read as a multiple axis accelerometer (see Chinchoy column 6, lines 12-17).

19. As to Claims 12 and 17, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 may be located in an implantable or external multi-chamber pulse generator (see Chinchoy Abstract and column 3, lines 35-46).

20. As to Claim 13, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 may be located in an implantable cardioverter-defibrillator (see Chinchoy column 1, lines 8-12 and column 8, lines 35-40).

21. As to Claim 14, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 further comprises a programmable medium 102 for executing computer readable instructions (see Chinchoy Fig. 2 and column 7, lines 29-47).

22. As to Claims 15 and 16, Chinchoy discloses that the computer readable medium 102 includes instructions for delivering a cardiac resynchronization therapy and delivery of pacing pulses to two or more heart chambers t by the selection of programmable pacing intervals, which can include atrial-atrial (A--A), atrial-ventricular (A-V), and ventricular-ventricular (V--V) intervals (see Chinchoy Title, Abstract and column 7, lines 29-59).

23. Claims 8 and 9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chinchoy.

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In addition to the arguments presented above, the Examiner takes the position that it is inherent, or at least obvious to one having ordinary skill in the art, that the additional mechanical sensor 60, located on right ventricular lead 32, may comprise one of a tensiometric-type sensor, a

single axis accelerometer and a multiple axis accelerometer since mechanical sensor 62 is capable of these embodiments and there appears to be no structural or operative difference between sensor 60 and sensor 62 from Chinchoy Fig. 1A, column 5, lines 50-67 and column 6, lines 1-41).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 4, 6-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann in view of Ferek-Petric (U.S. 5,271,392). As to Claims 4 and 6-7, Baumann discloses the claimed invention as discussed above except that the single mechanical sensor does not comprise one of a tensiometric-type sensor comprising a stylet transvenous delivery mechanism coupled to the tensiometric-type sensor.

Ferek-Petric, however, discloses a method for administering cardiac electrotherapy and an implantable electrotherapy apparatus employing myocardial a tensiometric-type transducer, read a sensor, to measure contractions of the heart muscle and subsequently control the administration of electrotherapy to the cardiac tissue (see Ferek-Petric Abstract). Ferek-Petric also discloses that the practical application of an accelerometer has the problems of oversensing of the human body acceleration which impedes accuracy, specifity and sensitivity of the sensor and that the radial acceleration of the lead at the point of accelerometer fixation is influenced by the intracardiac blood stream in such a way as to attenuate direct energy transfer from cardiac

muscle to the accelerometer (see Ferek-Petric column 4, lines 14-26) and that a system employing a tensiometric-type sensor eliminates the oversensing and blood-stream influence on the signal improving accuracy, specifity and sensitivity of the sensor and employs a direct transfer of cardiac contraction energy to the mechanical stretching energy within the sensor (see Ferek-Petric column 4, lines 34-49).

Ferek-Petric further discloses that there is the possibility to use a standard pacing lead for tensiometric measurement and that the stylet channel of a lead enables the control of the lead implantation by means of a stylet insertion. After the proper positioning of the lead tip, the stylet is pulled out therefore providing an empty stylet channel, which may be used for the permanent insertion of a tensiometric stylet (see Ferek-Petric Figs. 5-8 and column 5, lines 11-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor of Baumann in view of Ferek-Petric to include a tensiometric-type sensor comprising a stylet transvenous delivery mechanism coupled to the tensiometric-type sensor to improve the accuracy, specifity and sensitivity of the system and provide for control of the lead implantation by means of a stylet insertion.

26. As to Claim 13, Buamann discloses the claimed invention as discussed above except that the processor-based 34 electronic cardiac pacing engine 10 does not further comprise an implantable cardioverter-defibrillator.

Ferek-Petric, however, discloses a method for administering cardiac electrotherapy and an implantable electrotherapy apparatus employing myocardial a tensiometric-type transducer, read a sensor, to measure contractions of the heart muscle and subsequently control the administration of electrotherapy to the cardiac tissue (see Ferek-Petric Abstract). Ferek-Petric

further discloses that the method may be employed via an implantable cardioverter-defibrillator to improve detection and treatment of pathologic tachycardias and fibrillation (see Ferek-Petric column 1, lines 12-17) and lines 59-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the processor-based 34 electronic cardiac pacing engine 10 of Baumann in view of Ferek-Petric to comprise an implantable cardioverter-defibrillator to improve the invention's ability to detect and treat supraventricular tachycardia caused by atrial flutter or fibrillation.

27. Claims 6-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinchoy in view of Ferek-Petric. Chinchoy discloses the claimed invention as discussed above except that the tensiometric mechanical sensor(s) do not comprise a stylet transvenous delivery mechanism coupled to the tensiometric-type sensor.

Ferek-Petric, however, discloses a method for administering cardiac electrotherapy and an implantable electrotherapy apparatus employing myocardial a tensiometric-type transducer, read a sensor, to measure contractions of the heart muscle and subsequently control the administration of electrotherapy to the cardiac tissue (see Ferek-Petric Abstract). Ferek-Petric also discloses that the practical application of an accelerometer has the problems of oversensing of the human body acceleration which impedes accuracy, specifity and sensitivity of the sensor and that the radial acceleration of the lead at the point of accelerometer fixation is influenced by the intracardiac blood stream in such a way as to attenuate direct energy transfer from cardiac muscle to the accelerometer (see Ferek-Petric column 4, lines 14-26) and that a system employing a tensiometric-type sensor eliminates the oversensing and blood-stream influence on the signal improving accuracy, specifity and sensitivity of the sensor and employs a direct

transfer of cardiac contraction energy to the mechanical stretching energy within the sensor (see Ferek-Petric column 4, lines 34-49).

Ferek-Petric further discloses that there is the possibility to use a standard pacing lead for tensiometric measurement and that the stylet channel of a lead enables the control of the lead implantation by means of a stylet insertion. After the proper positioning of the lead tip, the stylet is pulled out therefore providing an empty stylet channel, which may be used for the permanent insertion of a tensiometric stylet (see Ferek-Petric Figs. 5-8 and column 5, lines 11-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensors of Chinchoy in view of Ferek-Petric to include tensiometric-type sensors comprising a stylet transvenous delivery mechanism coupled to the tensiometric-type sensor to improve the accuracy, specifity and sensitivity of the system and provide for control of the lead implantation by means of a stylet insertion.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chinchoy (U.S. 2004/0172079) discloses a system and method for monitoring left ventricular cardiac contractility and for optimizing a cardiac therapy based on left ventricular lateral wall acceleration (LVA) synonymous with Chinchoy (U.S. 6,885,889).

Chinchoy (U.S. 2004/0172078) discloses a system and method for monitoring left ventricular cardiac contractility and for optimizing a cardiac therapy based on left ventricular lateral wall acceleration (LVA) synonymous with Chinchoy (U.S. 6,885,889).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Supervisory Patent Examiner
Art Unit 3766

Jessica L. Reidel